IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

NEW YORK STATE RESTAURANT ASSOCIATION,

Plaintiff,

v.

Case No. 1:07-cv-05710 (RJH)

NEW YORK CITY BOARD OF HEALTH, NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE, and THOMAS R. FRIEDEN, in his official capacity as Commissioner of the New York City Department of Health and Mental Hygiene,

Defendants.

BRIEF OF *AMICI CURIAE* U.S. REPRESENTATIVE HENRY WAXMAN, FORMER FDA COMMISSIONER DAVID KESSLER, PUBLIC CITIZEN, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, AMERICAN COLLEGE OF PREVENTIVE MEDICINE, AMERICAN DIABETES ASSOCIATION, AMERICAN MEDICAL ASSOCIATION, AMERICAN PUBLIC HEALTH ASSOCIATION, CALIFORNIA CENTER FOR PUBLIC HEALTH ADVOCACY, THE MEDICAL SOCIETY OF THE STATE OF NEW YORK, TRUST FOR AMERICA'S HEALTH, AND PROFESSORS OF MEDICINE, NUTRITION AND PUBLIC HEALTH IN SUPPORT OF DEFENDANTS

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INTRODUCTION AND SUMMARY OF ARGUMENT

In adopting Health Code Regulation 81.50, which requires fast-food restaurants to post calorie information on their menus, New York City stepped into a regulatory gap that Congress intentionally left open to state and local governments when it enacted the Nutrition Labeling and Education Act (NLEA) in 1990.

Last year, a report commissioned by the FDA declared that "obesity has become a public health crisis of epidemic proportions." *The Keystone Forum on Away-from-Home Foods: Opportunities for Preventing Weight Gain and Obesity* (2006), at 1.[1] Echoing the consensus view of the U.S. Surgeon General, the National Academies' Institute of Medicine, and the American Medical Association, among others, the report concluded that "restaurants should provide consumers with calorie information in a standard format that is easily accessible and easy to use," allowing consumers to view the information "when standing at a counter, while reviewing a menu board, in a car when reading a drive-through menu, or when sitting down at a table reviewing a menu." *Id.* at 76, 77-78. The report acknowledged that "the FDA *does not have regulatory authority* to require nutrition information in restaurants," but that "state legislatures *do have the authority* to require the provision of nutrition information, and a number of these elected bodies have considered nutrition labeling bills [that] would require calories and/or other nutrition information to be listed on menus or menu boards." *Id.* at 74 (emphasis added).

In this lawsuit, the New York State Restaurant Association (NYSRA) asks the Court to hold that federal law preempts states and local authorities from doing what the federal government itself lacks authority to do—that Congress created a permanent regulatory vacuum. Congress did no such thing. To the contrary, Congress focused closely on the issues of preemption and coverage for

[1] *available at* http://www.cfsan.fda.gov/~dms/nutrcal.html ("*Keystone Report*"); *see also FDA Backgrounder,* http://www.cfsan.fda.gov/~lrd/bgowg2.html.

restaurants during its consideration of the NLEA and enacted carefully limited express preemption provisions that carved out room for state and local government to fill the gaps left by the statute. 21 U.S.C. § 343-1(a)(4); *id.* § 343(q)(5)(A)(i). As the legislation's chief sponsor in the Senate explained just moments before the final vote: "Because food sold in restaurants is exempt from the nutrition labeling requirements of [the NLEA], the bill does not preempt any State nutrition labeling requirements for restaurants." 136 Cong. Rec. S16607-02, S16608 (Oct. 24, 1990) (Sen. Metzenbaum). The FDA takes the same view. *See* FDA, *A Guide for Restaurants and Other Retail Establishments, available at* http://www.cfsan.fda.gov/~frf/qatext2.html ("[B]ecause the act exempts restaurant foods that do not bear a claim from mandatory nutrition labeling, State requirements for the nutrition labeling of such foods would not be preempted."). And although one would never know it from NYSRA's brief, this Court itself has held that state law requiring nutrition labeling of restaurant foods "is explicitly not pre-empted by the NLEA." *Pelman v. McDonald's Corp.*, 237 F. Supp. 2d 512, 526 (S.D.N.Y 2003).

NYSRA, however, contends that New York's rule is preempted because it is a requirement respecting "claims" of the type regulated by a different section of the NLEA. *See* 21 U.S.C. § 343-1(a)(5); *id.* § 343(r)(1)(A). That contention rests on a fundamental misunderstanding of the statutory scheme. The structure of the NLEA is premised on a distinction between requirements concerning straightforward nutritional information (such as a listing of a total number of calories), on the one hand, and requirements concerning descriptive "claims" that industry may choose to make about its food's nutritional content or health effects, on the other hand. The New York City rule is the former sort of rule: It is concerned only with purely factual information, not with descriptive "terms" that restaurants may use to make "claims" that "characterize" the nutrients in their food. That conclusion is supported by the Act's text and legislative history, by authoritative FDA interpretations, and by the statute as a whole. A contrary conclusion would lead to absurd results

and eviscerate the exception that Congress created for state regulation of restaurant nutrition labeling.

Hedging its bets, NYSRA argues that, even in the absence of express preemption, the New York rule is impliedly preempted by the NLEA, but that argument cannot be reconciled with Congress's command that the NLEA "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted" by the statute. Pub. L. No. 101-535, § 6(c), 104 Stat. 2535, 2364 (21 U.S.C. § 343-1 note). NYSRA also contends that the rule violates the First Amendment, but its position is incompatible with settled law and would turn the commercial speech doctrine upside down. *See Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 113-16 (2d Cir. 2001).

INTEREST OF *AMICI CURIAE*[2]

Amici are current and former public officials; consumer, medical, and public health organizations; and professors of medicine, nutrition, and public health, all of whom support New York City's Regulation 81.50. *Amici* include **U.S. Representative Henry Waxman,** who was the chief sponsor of the NLEA in Congress, and **David Kessler**, who served as the Commissioner of the U.S. Food and Drug Administration from 1990 to 1997, the period during which the key regulations implementing the NLEA were promulgated. **Public Citizen** is a non-profit advocacy organization with a longstanding interest in fighting exaggerated claims of federal preemption of state health and safety regulation and **Center for Science in the Public Interest** (CSPI) is a leading non-profit advocacy organization for nutrition and health, food safety, and sound science. CSPI was instrumental in getting Congress to consider nutrition labeling legislation in 1989 and in securing passage of the NLEA in 1990. CSPI also led the advocacy efforts on behalf of New York City's restaurant calorie labeling rule last year, and is working with other cities and states across the nation on similar measures.

[2] The identities and interest of *amici* are described more fully in an appendix to this brief.

The brief is also joined by the nation's leading medical and public health organizations. The **American Medical Association** is the largest professional association of physicians and medical students in the United States. In June 2007, the AMA specifically resolved that calorie content, in addition to other nutrition information, be displayed on menus and menu boards in fast-food and other chain restaurants. The AMA is joined by the **American College of Preventive Medicine**, which sponsored the resolution passed by the AMA's House of Delegates last month, and **The Medical Society of the State of New York**. The **American Diabetes Association** is a nation-wide non-profit organization founded in 1940 to advance the interests of the now nearly 21 million Americans with diabetes. The **American Public Health Association** is the oldest, largest and most diverse organization of public health professionals in the world and has been working to improve public health since 1872. The **California Center for Public Health Advocacy** is a non-profit organization established in 1999 by California's two public health associations to raise awareness about critical public health issues and is currently the lead supporter of a bill before the California State Legislature to require nutrition labeling on menus and menu boards in chain restaurants. The **Trust for America's Health** is a non-profit, non-partisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority.

Finally, *amici* include the following distinguished professors of medicine, nutrition, and public health: **George L. Blackburn**, Harvard Medical School; **Richard J. Decklebaum**, Columbia University; **Penny Kris-Etherton**, Pennsylvania State University; **Francine R. Kaufman**, University of Southern California Medical School; **Alice H. Lichtenstein**, Friedman School of Nutrition Science and Policy at Tufts University; **Marion Nestle**, New York University; **Barry M. Popkin**, University of North Carolina, Chapel Hill; and **Walter Willett**, Harvard School of Public Health and Harvard Medical School.

STATEMENT

I. THE BASIC STRUCTURE OF THE NLEA

The Nutrition Labeling and Education Act, Pub. L. No. 101-535, 104 Stat. 2535 (1990), produced groundbreaking changes in the way food is labeled in the United States, including requiring that nutrition labeling be placed on most packaged food, prohibiting the use of terms that characterize the level of nutrients in a food unless they conform to definitions established by FDA, and ensuring that claims about the relationship between nutrients and health conditions are supported by significant scientific agreement. The NLEA was introduced in the U.S. House of Representatives by Representative Henry Waxman on July 27, 1989, and signed into law by President George H.W. Bush on November 8, 1990. *See* 1990 U.S.C.C.A.N. 3354-1 (Nov. 8 1990) (Presidential signing statement). Although Congress extensively debated a number of issues—including preemption of state law and coverage for restaurants—the basic purpose and structure of the legislation remained the same over the course of the fifteen months during which it was considered.

A. The Distinction Between Nutrition Information Labeling and Unauthorized or Unsubstantiated Claims

Congress enacted the NLEA to serve two distinct but complementary purposes—first, "to clarify and to strengthen the Food and Drug Administration's legal authority to require nutrition labeling on foods," and second, "to establish the circumstances under which claims may be made about nutrients in foods." H.R. Rep. No. 538, 101st Cong., 2d Sess. 7 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3337 ("*House Report*"). To carry out these twin purposes, the NLEA added two subsections to the Federal Food, Drug and Cosmetic Act—section 343(q), which mandates specific, uniform disclosures that must be made on food labels, and section 343(r), which regulates the descriptive claims that manufacturers may choose to make about their foods. 21 U.S.C. §§ 343(q), 343(r). The first part of the Act sets forth general nutrition labeling requirements for the disclosure of factual nutritional information. The second part creates a framework for regulation by the FDA

concerning when and how food purveyors may make claims using terms that characterize the nutrient levels or health-related effects of their food. Put another way, the first section (§ 343(q)) tells food manufacturers or vendors what facts they must disclose about their food, while the second section (§ 343(r)) regulates the descriptive claims they may choose to make about their food.

1. Section 343(q): Mandatory Nutrition Labeling. The nutrition information labeling provisions of section 343(q) are the heart of the Act. Most American consumers are familiar with the "Nutrition Facts" panel, a uniform graphical chart that most food manufacturers must use to list "the total number of calories" in each serving of food, § 343(q)(1)(C), as well as the amounts of total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, and protein in the food, both as an "amount per serving" and, with the exception of sugars and protein, as a percent of a dietary reference value, called the "percent daily value." § 343(q)(1)(D); *see* 21 C.F.R. § 101.9. As discussed below, restaurant food is not covered by these federal requirements. 21 U.S.C. § 343(q)(5)(A)(i).

2. Section 343(r): Claims. In addition to requiring the disclosure of nutrition information, Congress also responded to the proliferation of dubious, misleading, and confusing claims made by food manufacturers about the nutrition and health effects of their foods. *House Report* at 3337.[3] That issue is taken up in the second part of the statute, section 343(r), which distinguishes between two kinds of claims: nutrient content claims (*e.g.* "low salt") and health-related claims (*e.g.* "fiber reduces the risk of cancer"). §§ 343(r)(1)(A), 343(r)(1)(B).

Prior to the NLEA's enactment, the FDA had general authority to prohibit false or misleading food advertising or labeling. § 343(a). Nevertheless, "an increasing number of food companies

[3] *See generally* Hutt, *A Brief History of FDA Regulation Relating to the Nutrient Content of Food*, in R. Shapiro, ed., *Nutrition Labeling Handbook* 1-27 (1995); Cooper, et al., *History of Health Claims Regulation*, 45 Food Drug Cosm. L.J. 655, 657 (1990); *FDA's Continuing Failure to Regulate Health Claims for Food: Hearings Before the Subcomm. on Human Resources and Intergovernmental Relations of the House Comm. on Gov't Relations*, 101st Cong., 2d Sess. (1989).

had turned to marketing . . . products bearing adjectival descriptors such as 'lite,' 'low,' 'reduced,' or 'fat free' because of their perception that such descriptors would lure consumers who thought such terms meant the products were more healthful." Sims, *The Politics of Fat: Food and Nutrition Policy in America* 202 (1998). In the absence of specific federal standards, these claims were often meaningless or misleading. *Id.* Congress aimed to address this problem by ensuring that such "content claims (such as 'low salt' or 'light') would have to be consistent with terms defined by the [FDA]." *House Report* at 3337.

Section 343(r) prohibits any "claim" on a food label that expressly or by implication "characterizes" the nutrient level of a food unless "the characterization of the level made in the claim uses terms which are defined in regulations of the [FDA]." § 343(r)(1)(A); § 343(r)(2)(A)(i). "An example of an express claim covered by [§ 343(r)] would be the statement 'low sodium.' An example of an implied claim covered by this section would be the statement 'lite,' which implies that the product is low in some nutrient (typically calories or fat), but does not say so expressly, or 'high oat bran,' which conveys an implied high fiber message." *House Report* at 3349 (section-by-section analysis). The FDA's regulations define nutrient content claims for terms including *free*, *low*, *high*, *good source*, *contains*, *provides*, *reduced*, *less*, *light* or *lite*, *modified*, and *more*. 21 C.F.R. §§ 101.13, 101.54, 101.56.[4]

[4] Section 343(r)(1) provides that "[a] statement of the type required by paragraph (q) . . . that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph." § 343(r)(1). The intent of this sentence was "to make it clear that the information on the nutrition label is not a claim under that provision and therefore is not subject to the disclosure requirements in section 403(r)(2)," although similar statements made outside the nutrition label could be subject to section 343(r) if they otherwise meet the definition of a "claim." 136 Cong. Rec. H5836-01, H5841 (July 30, 1990) (Rep. Waxman); *see also* 58 Fed. Reg. 2302, 2303-04 (Jan. 6, 1993); 21 C.F.R. § 101.13(c). Thus, statements relating to the amount of nutrients in a food can constitute "nutrient content claims" if they implicitly or explicitly "characterize" the amount of the nutrient.

FDA's regulatory authority under section 343(r) extends only to descriptive "claims" that manufacturers or vendors choose to make about their products. Factual statements that do not in any way "characterize" the level of nutrients, however, by definition do not fall within the statute's coverage. *See* 21 C.F.R. § 101.13(i)(3). The FDA explains the distinction as follows:

> The [NLEA] permits the use of label claims that characterize the level of a nutrient in a food (i.e., nutrient content claims) made in accordance with FDA's authorizing regulations. Nutrient content claims describe the level of a nutrient or dietary substance in the product, using terms such as *free*, *high*, and *low*, or they compare the level of a nutrient in a food to that of another food, using terms such as *more*, *reduced*, and *lite*. ***An accurate quantitative statement (e.g., 200 mg of sodium) that does not "characterize" the nutrient level may be used to describe any amount of a nutrient present.*** However, a statement such as "only 200 mg of sodium" characterizes the level of sodium as being low and would therefore need to conform to the criteria of an appropriate nutrient content claim or carry a disclosure statement that it does not comply with the claim.

FDA, *Claims that Can Be Made for Conventional Foods and Dietary Supplements* (2003) (emphasis in bold added), *available at* http://www.cfsan.fda.gov/~dms/hclaims.html.

With respect to health claims, section 343(r) uses the word "claim" in much the same way, to refer to statements manufacturers choose to make that "characterize" the relationship between the nutrients in their foods and diseases or health effects. § 343(r)(1)(B). Health claims, however, are regulated somewhat differently. Instead of providing a list of specific descriptive terms that manufacturers may use, FDA authorizes a health claim only when it determines that there is "significant scientific agreement" that scientific evidence supports the health claim. 21 C.F.R. § 101.14(c).

B. The NLEA's Exemption for Restaurant Foods from Federal Nutrition Labeling Requirements

The extent to which restaurants should or should not be covered by the NLEA's nutrition labeling requirements was a matter of considerable debate in Congress. Many of the legislation's supporters wanted restaurants foods to fall under section 343(q)'s nutrition labeling requirements, but such coverage "was vociferously opposed by the National Restaurant Association," Sim*s, Politics*

of Fat, at 200, and was not included in the final legislation. *See* § 343(q)(5)(A)(i) (exempting food that is "served in restaurants" from the nutrition labeling requirements of section 343(q)). As far as federal law is concerned, restaurants are not required to provide the kind of nutritional information—such as listings of the calories or fat in all food items—that is required of packaged foods.[5]

Thus, the only circumstance in which the NLEA affects restaurants is when they make "claims," within the meaning of section 343(r), that "characterize" the nutrients in the foods they serve—for example, when a restaurant's menu describes an item as "low fat." 21 C.F.R. § 101.10; *see* FDA Talk Paper T96-52 (July 30, 1996), *available at* http://www.cfsan.fda.gov/~lrd/tpmenus.html ("This final rule affects only those restaurateurs who place claims such as 'low fat' or 'heart healthy' on their menus.").[6] A restaurant that makes such a descriptive claim is obligated only to disclose "the nutrient amounts that are the basis for the claim." 21 C.F.R. § 101.10. Such quantitative

[5] In 2004, the FDA's Obesity Working Group explained the implications of the regulatory gap left open by section 343(q)'s exemption for restaurant food: "[U]nder the laws administered by FDA, restaurants are not required to provide nutrition information unless a nutrient content or health claim is made for a food or meal. When claims are made, however, the restaurant need only provide information about the amount of the nutrient that is the subject of the claim. Restaurants may, and many do, provide nutrition information on a voluntary basis. Nevertheless, this nutrition information is often in the form of posters, placemats or menu icons, or on the Internet, rather than at the point-of-sale. Such information is not always readily available or observable at the point-of-sale." FDA, *Calories Count: Report of the Working Group on Obesity* (2004), at Part V.B., *available at* http://www.cfsan.fda.gov/~dms/owg-toc.html ("*FDA Calories Count Report*").

[6] FDA originally decided to exempt restaurant menus—but not restaurant signs, placards or posters—from its regulations implementing section 343(r). 58 Fed. Reg. 2066 (Jan. 6, 1993). In response to a lawsuit filed by Public Citizen and Center for Science in the Public Interest, FDA reversed course just six months later and issued proposed regulations to remove the menu exemption, 58 Fed. Reg. 33055 (June 15, 1993), but the regulations were rejected by the White House Office of Management and Budget under pressure from the restaurant industry. *See* Sims, *Politics of Fat*, at 201. The court in that lawsuit ultimately held that the menu exemption was contrary to the NLEA, *Public Citizen v. Shalala*, 932 F. Supp. 13 (D.D.C. 1996), and, about one month later, the agency issued a final rule that adopted its June 1993 proposal. *See* 61 Fed. Reg. 40320 (Aug. 2, 1996) (adopting final rule).

declarations are considered the "functional equivalent" of the type of nutritional labeling required of packaged foods. *Id.*

C. The NLEA's Preemption Provisions

Congress also devoted careful attention to the subject of preemption during its consideration of the NLEA. *See* Sims, *Politics of Fat*, at 199 ("The preemption issue remained a key area of dispute throughout consideration of the food labeling bill, with the basic issue being how far the legislation should go in setting uniform food labeling regulations that preempt state laws.").[7] In the final moments of the floor debate before the NLEA was formally adopted by the House after its passage in both chambers, Representative Waxman explained that carefully limited federal preemption had been added to the bill to induce industry to support the legislation. 136 Cong. Rec. H12951-02, H12954 (Oct. 26, 1990) ("[I]t was decided that the fairest way to expect the food industry to support a nutrition labeling bill, was to give them *some types of preemption* of *some* burdensome State laws that interfered with their ability to do business in all 50 States.") (emphasis added). Even Senator Orrin Hatch, who was the leading proponent of stronger federal preemption, conceded that "the carefully crafted uniformity section of this legislation is limited in scope." 136 Cong. Rec. S16607-02, S16611 (Oct. 24, 1990).

In an effort to satisfy industry concerns while remaining "sensitive to the regulatory roles played by the States," the Senate reached a compromise that was "refined to provide national uniformity where it is most necessary, while otherwise preserving State regulatory authority where it is appropriate." 136 Cong. Rec. S16607-02, S16609 (Oct. 24, 1990) (Sen. Mitchell); see also 136 Cong. Rec. S16607-02, S16611 (Oct. 24, 1990). (Sen Hatch) ("[T]he compromise makes clear that

[7] *See generally* Bradley, *The States' Role in Regulating Food Labeling and Advertising: The Effect of the Nutrition Labeling and Education Act of 1990*, 49 Food & Drug L.J. 649, 659 (1994); Jordan, *Preemption and Uniform Enforcement of Food Marketing Regulations*, 49 Food & Drug L.J. 401, 401 (1994).

the national uniformity in food labeling that is set forth in the legislation has absolutely no effect on preemption of State or local requirements that relate to such things as warnings about foods or components of food."). That default position—of "otherwise preserving State regulatory authority"—is reflected in a special rule of construction limiting the preemptive effect of the NLEA to only state laws that fall within the NLEA's express preemption provisions:

> The Nutrition Labeling and Education Act of 1990 shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A [21 U.S.C. § 343-1(a)] of the Federal Food, Drug, and Cosmetic Act.

Pub. L. No. 101-535, § 6(c), 104 Stat. 2535, 2364 (21 U.S.C. § 343-1 note).

Given its exemption of restaurant food from NLEA's nutrition labeling regime, Congress specifically considered the question of state and local authority to regulate nutrition labeling in restaurants. The final legislation contained a preemption provision that was carefully drafted to preempt any "requirement for nutrition labeling of food that is not identical to" section 343(q), "*except* a requirement for nutrition labeling of food which is exempt" from section 343(q)—that is, *except* a requirement for nutrition labeling of restaurant food. § 343-1(a)(4) (emphasis added). On the day that the NLEA passed the Senate by a voice vote, the Act's chief Senate sponsor, Senator Howard Metzenbaum, explained the meaning of this exception:

> Because food sold in restaurants is exempt from the nutrition labeling requirements of section 403(q)(1)-(4), *the bill does not preempt any state nutrition labeling requirements for restaurants.*

136 Cong. Rec. S16607-02, S16608 (Oct. 24, 1990) (Sen. Metzenbaum) (emphasis added).

ARGUMENT

I. A STRONG PRESUMPTION AGAINST PREEMPTION APPLIES IN THIS CASE.

In seeking a ruling from this court that New York City Health Code Regulation § 81.50 is preempted by federal law, NYSRA bears an especially heavy burden. "[B]ecause the States are independent sovereigns in our federal system," federal courts must presume "that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (internal quotation marks omitted); *see Rogers v. Consolidated Rail Corp.*, 948 F.2d 858, 859 (2d Cir. 1991) ("Pre-emption of state law by federal statute or regulation is not favored 'in the absence of persuasive reasons—either that the nature of the regulated subject matter permits no other conclusion, or that the Congress has unmistakably so ordained.'") (quoting *Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981)). That presumption is rooted in an imperative of federalism implicit in the constitutional plan and embodied, among other places, in the Tenth Amendment. An insistence on "clear and manifest" Congressional intent "provides assurance that the 'federal-state balance' will not be disturbed unintentionally by Congress or unnecessarily by the courts." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (quoting *United States v. Bass*, 404 U.S. 336, 349 (1971)); *see generally* Grey, *Make Congress Speak Clearly*, 77 B.U. L. Rev. 559 (1997); Hoke, *Preemption Pathologies and Civic Republican Values*, 71 B.U. L. Rev. 685 (1991).[8]

[8]NYSRA urges this Court to strike down New York's rule because it regards it as a novel "social science experiment" aimed at solving a problem (the obesity epidemic) for which nobody has found a "magic bullet." Br. at 3. But, as Justice Brandeis famously observed, one of the chief virtues of our system of federalism is that "a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932). It is precisely when "disagreement exists about how best to accomplish [a] goal" that "the theory and utility of our federalism are revealed, for the States may perform their role as laboratories for experimentation to devise various solutions where the best solution is far from clear." *United States v. Lopez*, 514 U.S. 549, 581 (1995)

The City's regulation "falls squarely within its prerogative to regulate matters of health and safety, which is a sphere in which the presumption against preemption applies, indeed, stands at its strongest." *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 94 (2d Cir. 2007) (discussing preemption in context of food and drug law); *see Medtronic,* 518 U.S. at 485. Federal courts presume "that state and local regulation of health and safety matters can constitutionally coexist with federal regulation" because "the regulation of health and safety matters is primarily, and historically, a matter of local concern." *Hillsborough County v. Automated Med. Labs., Inc.,* 471 U.S. 707, 719 (1985). "[T]here is indeed no subject of legislation more firmly identified with local affairs than the regulation of restaurants." *District of Columbia v. John R. Thompson Co.*, 346 U.S. 100, 113 (1953).

Any analysis of the scope of federal preemption must be guided by the principle that "the purpose of Congress is the ultimate touchstone in every preemption case." *Medtronic*, 518 U.S. at 485 (internal quotation marks omitted). That purpose, of course, is discerned primarily "from the language of the pre-emption statute and the statutory framework surrounding it." *Id.* at 486 (internal quotation marks omitted). In addition, the Court must examine the "structure and purpose of the statute as a whole, as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." *Id.* (internal citations and quotation marks omitted). Here, the analysis must begin and end with the carefully limited language of the NLEA's express preemption clause because Congress made clear that "the Nutrition Labeling and Education Act of 1990 shall not be construed to preempt any provision of State law, unless such provision is expressly preempted" by that language. Pub. L. No. 101-535, § 6(c), 104 Stat. 2535, 2364 (21 U.S.C.

(Kennedy, J., concurring); *see generally* Hills, *Against Preemption: How Federalism Can Improve the National Legislative Process*, 82 N.Y.U. L. Rev. 1 (2007). The solution New York is pursuing here, moreover, is one that is supported by an growing scientific and public policy consensus. *See* Br. of *Amici* City and County of San Francisco, *et al.*

§ 343-1 note); *see AT&T Communications of Ill., Inc. v. Ill. Bell Tel. Co.*, 349 F.3d 402, 410 (7th Cir. 2003). Thus, the Court's only task is to determine whether New York City's rule falls within "'the domain expressly pre-empted' by that language." *Medtronic*, 518 U.S. at 484 (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)). To the extent that there is any ambiguity—and, as explained below, there is none—this Court has a "duty" to adopt a plausible reading of the statute that preserves local autonomy. *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) ("[I]ndeed, even if its alternative were just as plausible as our reading of that text . . . we would nevertheless have a duty to accept the reading that disfavors pre-emption."); *Ace Auto Body & Towing, LTD v. City of New York*, 171 F.3d 765, 776 (2d Cir. 1999).

II. THE NLEA LEAVES STATES FREE TO REQUIRE NUTRITION LABELING OF RESTAURANT FOOD.

The NLEA requires that manufacturers disclose specific nutrition information about most food products sold in the United States, including "nutrition information that provides . . . the total number of calories . . . derived from any source . . . in each serving size or other unit of measure of the food." § 343(q)(1)(C)(i). Under NLEA's preemption provision, states and local governments are *not* free, as a general matter, to adopt "any requirement for nutrition labeling of food" that is not "identical" what federal law requires. § 343-1(a)(4). Thus, New York City clearly could not adopt a rule requiring cereal boxes or cans of soup sold in local grocery stores to display the City's own version of the federal "Nutrition Facts" panel.

But Congress, seeking to avoid a regulatory vacuum, intentionally excepted state requirements for nutrition labeling of restaurant food from NLEA preemption at the same time that it exempted restaurant food from the new federal labeling requirements. The NLEA preempts "any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) . . . *except a requirement for nutrition labeling of food which is exempt*" under that section—i.e., a requirement for nutrition labeling of restaurant food. § 343-1(a)(4) (emphasis added); *see* § 343(q)(5)(A)(i)

(providing that section 343(q)'s nutrition labeling requirements "shall not apply to food . . . which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments"). Taken together, these three provisions—sections 343-1(a)(4), 343(q)(5)(A)(i) and 343(q)(1)(C)(i)—demonstrate that Congress intended that the NLEA would not preempt state requirements "for nutrition labeling"—including labeling "that provides . . . the total number of calories"—for "food . . . which is served in restaurants." Indeed, this Court has already rejected the proposition that the NLEA preempts a requirement that restaurants disclose nutritional information about their food. *See Pelman,* 237 F. Supp. 2d at 526 ("A finding that a lack of nutritional labeling on McDonalds' products violates [New York law] therefore is explicitly not pre-empted by the NLEA.").

The legislative history fully supports a common sense interpretation of the statute's text. Senator Howard Metzenbaum of Ohio, the chief sponsor of the NLEA in the Senate, could hardly have been clearer on this point:

> Because food sold in restaurants is exempt from the nutrition labeling requirements of section 403(q) (1)-(4) [343(q)(1)-(4)], *the bill does not preempt any State nutrition labeling requirements for restaurants.*

136 Cong.Rec. S16607-02, S16608 (Oct. 24, 1990) (Sen. Metzenbaum) (emphasis added).

The FDA is of the same view. *See* FDA, *A Guide for Restaurants and Other Retail Establishments, available at* http://www.cfsan.fda.gov/~frf/qatext2.html ("*Question:* Can a State require restaurant foods to bear nutrition labeling even if the food is exempt under Federal requirements? *Answer:* Yes . . . [B]ecause the act exempts restaurant foods that do not bear a claim from mandatory nutrition labeling, State requirements for the nutrition labeling of such foods would not be preempted.").

NYSRA (at 10 n.2) attempts to downplay this unequivocal FDA statement as "outdated" because the *Guide for Restaurants* was issued in 1995, before the agency's 1996 regulations implementing section 343(r)'s "claims" requirements as applied to restaurant menus (*see* n.7, *infra*). But the

issue of coverage for menus under section 343(r) is entirely beside the point. The FDA statement specifically distinguishes between "mandatory nutrition labeling" of the type required under section 343(q)—from which restaurant food is exempt—and "foods that bear a claim" under section 343(r), and follows the common sense reading of the statute discussed above. Moreover, subsequent FDA and FDA-sponsored publications are fully consistent with the 1995 statement, s*ee, e.g., Keystone Report* at 74; *FDA Calories Count Report* at V.B, and NYSRA does not contend otherwise.

Conspicuously absent from the NYSRA's brief is any explanation for why the Court should ignore the clear evidence of Congressional intent, in the final clause of section 343-1(a)(4), *not* to preempt nutrition labeling requirements for restaurant food. "That Congress added the remainder of the provision is evidence of its intent to draw a distinction between state labeling requirements that are pre-empted and those that are not." *Bates*, 544 U.S. at 449.

In sum, not only is there no "clear and manifest" evidence of Congressional intent to preempt restaurant labeling regulations like New York's, *Medtronic*, 518 U.S. at 485, but the clearest evidence of Congressional intent—in the form of statutory language, legislative history, and agency interpretation, all addressing precisely the question of preemption of state nutrition labeling requirements for restaurant food—points decisively away from preemption.

III. NEW YORK'S RULE HAS NOTHING TO DO WITH THE TYPE OF DESCRIPTIVE "CLAIMS" REGULATED BY THE NLEA.

In an effort to sidestep Congress's exclusion of local restaurant nutrition labeling requirements from express preemption under the NLEA, NYSRA turns instead to a different section of the Act, section 343(r), which prohibits unauthorized or unsubstantiated descriptive "claims" about food, and its companion preemption provision. *See* § 343(r) (prohibiting any "claim" that "characterizes" the nutrient content of food unless the "characterization" employs specific "terms" defined by the FDA); § 343-1(a)(5) (preempting state law "respecting any claim of the type described in section 343(r)"). For its express preemption argument to be plausible, the Restaurant Association must

demonstrate that New York Health Code Regulation § 81.50 a "requirement respecting any claim of the type described in section 343(r)." § 343-1(a)(5). The Restaurant Association's argument is creative, but the bottom line is that New York City's rule has nothing to do with such "claims." The New York rule neither prevents restaurants from making, nor requires them to make, nor limits the circumstances under which they may make, descriptive claims characterizing the nutrient content or health effects of their food. Restaurants in New York remain just as free as they were in the past to make such descriptive claims, so long as they comply with federal law.

New York's calorie labeling rule requires only that certain restaurants "post on menu boards and menus the calorie content values . . . for each menu item next to the listing of each menu item." 24 RCNY Health Code Reg. § 81.50(b). Although its brief is not entirely clear on this point, NYSRA appears to concede that a nutrient content claim of the type described in section 343(r) must be "voluntarily made by the restaurant" (Br. at 9) and, thus, that the factual disclosures required by Regulation 81.50 would not themselves constitute "claims" within the meaning of section 343(r). Hence, if the City were to adopt a regulation requiring *all restaurants* in the City to disclose calorie content information on their menus, even under NYSRA's theory, that requirement presumably would *not* be preempted by federal law.

Instead, NYSRA's theory appears to be that New York's rule is preempted because it is more narrowly tailored. Specifically, to make the regulation less burdensome, the City limited Regulation 81.50's coverage only to menu items that are (a) "served in portions the size and content of which are standardized" and (b) "for which calorie content information is made publicly available on or after March 1, 2007, by or on behalf of the food service establishment serving the items." 24 RCNY Health Code Reg. § 81.50(a). NYSRA's position appears to be premised on an assertion that *any* publication of "calorie content information" within the meaning of the New York rule is equivalent to the type of "claim" regulated by section 343(r). *See* NYSRA Br. at 13 ("There can be

no doubt that Regulation 81.50 imposes requirements 'respecting any claim of the type described in section 343(r)(1)' because publishing calorie content is a nutrition content claim under that section.").[9] As explained below, that assertion is at odds with section 343(r)'s text, authoritative FDA interpretations, the legislative history, and the structure of the NLEA as a whole. NYSRA's construction would also lead to absurd results and would threaten to swallow the exception that Congress intentionally created for state restaurant-labeling requirements.

1. The Text of the Statute. New York's rule is not a requirement respecting any "claim of the type described in section 343(r)," § 343-1(a)(4), because it is not a requirement respecting "claims" at all. The word "claim," read in the context of section 343(r) and the NLEA as a whole, refers to a qualitative assertion in need of substantiation—that is, "an assertion, statement, or implication (as of value, effectiveness, qualification, eligibility) often made or likely to be suspected of being made without adequate justification," for example: "his claims to sound scholarship," or "appraising the authenticity of some dealer's claims." *Webster's Third New International Dictionary* 414 (1965). A company making a "claim" is not simply making a straightforward factual disclosure but is

[9] Because this is a facial challenge, NYSRA cannot meet its burden merely by speculating about scenarios under which the City might construe the phrase "calorie content information" to encompass descriptive food claims. The Court may not "rest [its] decision on consequences that, while possible, are by no means predictable." *Dep't of Taxation and Fin. of N.Y. v. Milhelm Attea & Bros., Inc.*, 512 U.S. 61, 69 (1994); *see PhRMA v. Concannon*, 249 F.3d 66, 77-78 (1st Cir. 2001), *aff'd sub. nom. PhRMA v. Walsh*, 538 U.S. 644 (2003). "A facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid." *United States v. Salerno*, 481 U.S. 739, 745 (1987); *see also Calif. Coastal Comm'n v. Granite Rock Co.*, 480 U.S. 572, 579-80 (1987); *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982) ("The existence of a hypothetical or potential conflict is insufficient to warrant the preemption of the state statute."). And in any event, NYSRA lacks standing to mount a challenge based on hypothetical "claims" that NYSRA's members might make in the future. *See Nutritional Health Alliance v. Shalala*, 144 F.3d 220, 225-227 (2d Cir. 1998) (challenge to health-claims regulation was not ripe where "plaintiffs' complaint did not allege any particular health claims that plaintiffs wished to state"); *Nutritional Council for Improved Health v. Shalala*, 122 F.3d 878, 884 (10th Cir. 1997) (no standing where "[p]laintiffs do not advance a single claim they wish to make . . . which could be prohibited under the health claims regulations").

instead offering an assertion, statement, or implication that its food has some quality (related to a nutrient level or health effect) that the manufacturer believes will make the food desirable to consumers.

Because companies were frequently making such statements without adequate justification prior to NLEA's passage, Congress delegated authority to the FDA to regulate the circumstances under which such claims may be made, to ensure that they are made justifiably and in a manner consumers can understand. *See* 136 Cong. Rec. H5836-01, H5840 (July 30, 1990) (Rep. Waxman) ("Today, companies use terms such as 'low' and 'light' inconsistently. On some products, 'light' means low in fat; on others, such as some brands of olive oil, it refers to the color of the product. The bill would correct this deceptive and misleading state of affairs by requiring that terms such as 'light' have a single meaning."). For nutrient content claims, section 343(r) creates a mechanism whereby such "content claims" must "be consistent with terms defined" by the FDA. *Id.* For health claims, the FDA will only allow foods to bear claims about the links between foods and diseases if the claim is shown to be substantiated by significant scientific agreement, either through a rulemaking by FDA or an authoritative statement, by a federal agency with relevant scientific expertise, to which FDA does not object. § 343(r)(4); 21 C.F.R. § 101.14(c). But New York's rule is concerned only with straightforward factual information concerning the amount of calories in food items; it has nothing to do with regulating such potentially unsubstantiated or confusing assertions.

Even if factual disclosures of calorie information might otherwise constitute "claims," they are not claims that use descriptive "terms" to "characterize" a nutrient level within the meaning of section 343(r), and thus would not be a "claim of the type described in section 343(r)." § 343-1(a)(5). Section 343(r) covers a "claim" made on a food label that "characterizes" the level of a nutrient or the relationship of a nutrient to a disease or health-related condition, providing that such claims "may be made only if the characterization of the level made in the claim uses terms which are

defined in regulations of the [FDA]." §§ 343(r)(1), 343(r)(2)(A)(i). Section 343(r) uses the word "characterize" in the sense of "to describe the character or individual quality of," as in, for example, "He characterized her in a few well-chosen words." *American Heritage Dictionary of the English Language*, 4th ed. (2006); *see also Webster's Third New International Dictionary* 376 (1965) (defining "characterize" as "to describe the essential character or quality of"). Thus, factual statements that do not implicitly or explicitly use "terms" to "characterize" the nutrient content of food are not "claims" of the type described in section 343(r).

2. FDA Regulations, Guidance, and Enforcement Letters. The FDA's regulations—which are entitled to deference, *Hillsborough County*, 471 U.S. at 714-15—are consistent with that interpretation. The regulations define a nutrient content claim as "[a] claim that expressly or implicitly characterizes the level of a nutrient of a type required to be in nutrition labeling under [the regulations implementing 343(q)]." 21 C.F.R. § 101.13(b). The regulations go on to provide an extensive dictionary of "terms" that "characterize" nutrient levels—including *light*, *lite*, *high*, *rich in*, *excellent source of*, *good source of*, *contains*, *provides*, *more*, *fortified*, *enriched*, *added*, *extra*, and *plus*. 21 C.F.R. §§ 101.54-101.69; *see also* FDA, *Definitions of Nutrient Content Claims, Food Labeling Guide—Appendix A*, http://www.cfsan.fda.gov/~dms/flg-6a.html; FDA, *Label Claims: Nutrient Content Claims*, http://www.cfsan.fda.gov/~dms/lab-nutr.html.

Although NYSRA's brief devotes scant attention to the threshold question of whether New York's rule is a requirement concerning claims of the type described in section 343(r), it twice quotes a snippet of the relevant FDA regulation, which lists the phrase "contains 100 calories" as an example of an expressed nutrient content claim that might be made by a food manufacturer. 21 C.F.R. § 101.13(b)(1). That regulation, NYSRA suggests, supports the proposition that any "statements about calories are 'nutrient content claims' within the meaning of the NLEA" (Br. at 10) and are thus governed by section 343(r) and its implementing regulations.

In fact, the regulation that NYSRA cites undermines rather than supports its express pre-emption argument. Again, that regulation make clear that section 343(r) extends only to a "claim that expressly or implicitly *characterizes* the level of a nutrient," 21 C.F.R. 101.13(b) (emphasis added), and thus confirms that a statement is a claim within the meaning of section 343(r) only if it uses descriptive terms—such as "low," "more" or "contains"—to characterize the level of nutrients. *See, e.g.*, 21 C.F.R. 101.54(c) (listing "contains" as a descriptive term and limiting its use).

More to the point, and in keeping with the plain meaning of the word "characterize," the same regulation that NYSRA cites makes clear that section 343(r) does not extend to straightforward listings of calorie amounts that are not accompanied by statements that implicitly "characterize" the calorie content. "The label or labeling of a product may contain a statement about the amount of percentage of a nutrient if:"

> (3) The statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect (e.g., "100 calories" or "5 grams of fat"), in which case no disclaimer is required.

21 C.F.R. § 101.13(i)(3).[10] Notably, the regulation uses the bare phrase "100 calories" as an illustration of a statement about the "amount or percentage of a nutrient" that does *not* "characterize" a nutrient level. Again using "100 calories" as an example, the FDA explained the reasoning for the regulation as follows:

> [B]ased on the comments and its review of the 1990 amendments, FDA finds that there are some circumstances in which an amount claim cannot be considered to characterize in any way the level of a nutrient in a food. For example, the statement "100 calories" or "5 grams of fat" on the principal display panel of a food would be a simple statement of amount that, by itself, conveys no implied characterization of the level of the nutrient.

[10]The qualification that a statement may not be "false or misleading in any respect" is a reference to FDA's general authority, under section 343(a), to regulate false or misleading food advertising or labeling. Notably, the NLEA does not list section 403(a) among the provisions of the statute that preempt state law. *See* Jordan, *Preemption and Uniform Enforcement*, 49 Food & Drug L.J. at 402.

58 Fed. Reg. 2302-01, 2310 (Jan. 6, 1993).

FDA's guidance concerning its regulations expands on the same point: "Nutrient content claims describe the level of a nutrient or dietary substance in the product, using terms such as *free*, *high*, and *low*, or they compare the level of a nutrient in a food to that of another food, using terms such as *more*, *reduced*, and *lite*. An accurate quantitative statement (e.g., 200 mg of sodium) that does not 'characterize' the nutrient level may be used to describe any amount of a nutrient present." FDA, *Claims that Can Be Made for Conventional Foods and Dietary Supplements* (2003) (emphasis added), *available at* http://www.cfsan.fda.gov/~dms/hclaims.html; *see also* Guarino, *Nutrient Descriptor and Disease Claims for Foods*, 48 Food & Drug L.J. at 671 (discussing 21 C.F.R. 101.13(i)(3)).

If any further confirmation is needed that straightforward calorie content information falls outside the scope of section 343(r), it can be found in FDA enforcement letters, a few of which are attached as an appendix to this brief. In one of the attached letters, FDA responded to a request from *amicus* Center for Science in the Public Interest (CSPI) urging the agency to regulate products bearing the statement "0 *trans* fat." *See* Letter to M. Jacobson from B. Schneeman, dated Apr. 14, 2006. The FDA letter noted that CSPI had "refer[red] to these statements (i.e., '0g *trans* fat') as claims" and acknowledged that "there are no approved nutrient content claims for *trans* fat." *Id.* at 1. Nevertheless, the agency rejected the request on the grounds that such bare factual statements concerning the amount of nutrients are not claims at all:

> [T]he label of labeling may contain a factual statement about the amount or percentage of a nutrient in accordance with 21 C.F.R. 101.13(i)(3). The use of this kind of factual statement should not in any way imply that there is a little or a lot of the nutrient in the food and is not false or misleading under section 403(a) of the Act. . . . . The use of descriptive words, such as 'only' or 'contains,' would implicitly characterize the level of the nutrient for which there is no definition. A claim that expressly or implicitly characterizes the level of a nutrient may not be made on the label or labeling foods unless the claim is made in accordance with the regulations (21 C.F.R. 101.13(b)).

> ***The '0g trans fat' statements presented in your letter are considered factual statements, rather than nutrient content claims***, in accordance with § 101.13(i)(3) and the products are not considered misbranded under the Act.

Id. at 2 (emphasis added).

3. The Legislative History. The legislative history also overwhelmingly confirms that Congress intended section 343(r)(1)(A) to mean what it says—that it encompasses only "claims" that use descriptive "terms" to "characterize" nutrient levels. In presenting a revised version of the bill before the House, Representative Waxman explained that the statute had "been amended to provide that restaurants that use *content descriptors* in connection with the sale of food (for example, the use of the word 'light' or 'low' on the menu) must comply with regulations issued by the Secretary under section [section 343(r)]." 136 Cong. Rec. H5836-01, H5841 (July 30, 1990) (emphasis added).

The legislative history is sprinkled throughout with similar references, describing section 343(r) as regulating "certain descriptor words," "special nutritional claims," and "terms that are used when products are advertised as being 'light,' or 'free,' or 'high.'" *See, e.g.*, 136 Cong. Rec. H12951-02, H12953-54 (Oct. 26, 1990) (Rep. Madigan) ("Regarding nutrition claims on foods, the bill requires that content claims such as light, low, et cetera, would have to be consistent with terms defined by the FDA. This is to address the current problem of companies using these terms differently and inconsistently. "); 136 Cong. Rec. S16607-02, S16608 (Oct. 24, 1990) (Sen. Metzenbaum) (describing "the Secretary's responsibility under the bill to regulate nutrition content claims which use certain 'descriptor' words, like 'low-fat' and 'light.' The Secretary is required to define in regulations the terms which may be used to characterize the level of a nutrient in food."); *id.* at S16609 (Sen. Mitchell) (describing the purpose of section 343(r) to "regulate the use of special nutritional claims that may appear on food packages. These rules will apply to such terms as 'lite' and 'reduced,' as well as regulating specialized claims regarding the effect of certain nutrients on disease-such as 'reduces the risk of cancer.'"); *id.* at S16610 (Sen. Hatch) ("Today, there is confusion

about terms that are used when products are advertised as being 'light,' or 'free,' or 'high.' By virtue of this compromise, the Secretary will define specific terms within a set period of time."). By contrast, the legislative history does not support NYSRA's odd construction of the statute, in which a "claim" under section 343(r) would apparently include even the blandest of disclosures that "characterize" nothing.

4. ***The Statutory Scheme as a Whole.*** NYSRA's unorthodox construction of section 343(r) is also incompatible with the statutory scheme as a whole. Under NYSRA's construction, Congress's decision not to preempt state and local restaurant labeling requirements is greatly undermined, and the statute's distinction between descriptive "claims" and any other kinds of statements—even straightforward factual disclosures—collapses. NYSRA offers no principled basis for distinguishing between the sphere of regulation of nutritional information in restaurants that Congress expressly left open to state and local regulation in section 343-1(a)(4) (the companion preemption provision to section 343(q)), and the types of regulations respecting "claims" within the meaning of sections 343-1(a)(5) (the companion preemption provision to section 343(r)).

NYSRA's interpretation of the statute would also lead to absurd results in more specific ways. The FDA rule on which NYSRA relies most heavily, 21 C.F.R. § 101.10, provides that a restaurant that makes a descriptive claim of the type covered by section 343(r) must disclose "the nutrient amounts that are the basis for the claim," which are considered the "functional equivalent" of the type of nutritional labeling required of packaged foods. 21 C.F.R. § 101.10. But under NYSRA's construction, there would apparently be no difference between the type of claim that triggers the regulation in the first place and the factual disclosure that must accompany the claim as a result. Another FDA rule, 21 C.F.R. § 101.60, implements section 343(r) by defining nutrient content claims for the calorie content of foods. The rule provides that "[a] claim about the calorie or sugar content of a food may only be made on the label or labeling of a food if . . . [t]he claim uses

the terms defined in this section in accordance with the definition for that term," and goes on define such terms as *low calorie* and *reduced calorie* and the circumstances under which they may be used. *Id.* § 101.60(a)(1). If NYSRA's construction of section 343(r) were correct, neither a manufacturer of packaged food nor a restaurant could truthfully disclose in a straightforward, non-descriptive manner the number of calories in a food (outside of the labeling required by section 343(q)), because that would constitute a "claim" about the calorie content of the food that does not use one of the defined terms. The more sensible reading, of course—and the one adopted by the FDA—is that the disclosure of such calorie content information does not constitute a "claim" within the meaning of section 343(r) in the first place. *See* 21 C.F.R. § 101.13(i)(3).

In short, New York's calorie labeling law does not come close to addressing "claims" that restaurants may decide to make about their food, let alone claims that "characterize" nutrient levels using descriptive "terms" of the type regulated by section 343(r) and its implementing regulations. Rather, New York's rule mandates nutrition labeling for certain restaurant food, just as section 343(q) mandates nutrition labeling for packaged food, and thus falls squarely into the sphere that Congress intentionally left open to the states.

IV. THE NLEA FORECLOSES IMPLIED PREEMPTION.

NYSRA's implied preemption argument (at 16-18) is incompatible with Congress's command that "[t]he Nutrition Labeling and Education Act of 1990 shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A [21 U.S.C. § 343-1(a)] of the Federal Food, Drug, and Cosmetic Act." § 343-1 note (Pub. L. No. 101-535, § 6(c), 104 Stat. 2535, 2364 (1990)). As the FDA has explained, this statutory language "clearly manifests Congress's intention that the 1990 amendments" are not to preempt state law beyond the NLEA's express terms: "If there is no applicable Federal requirement that has been given preemptive status by Congress, there is no competing claim of jurisdiction, and, therefore, no basis under

the 1990 amendments for Federal preemption." 56 Fed. Reg. 60528-0, 60530 (Nov. 27, 1991); *accord* Institute of Medicine, *Food Labeling: Toward National Uniformity* 68 (1992) (Congressionally-mandated study on NLEA preemption). Thus, "the only State requirements that are subject to preemption are those that are affirmatively different on *matters that are covered* by section [343-1] of the act." 58 Fed. Reg. 2462-01 (Jan. 6, 1993) (emphasis added). In this respect, the NLEA's preemption provisions are "somewhat unusual. The NLEA can be analyzed only in terms of express preemption, because its express provisions prohibit any implied preemption under the statute." Burk, *The Milk-Free Zone, Federal and Local Interests*, 22 Colum. J. Envt'l L. 227, 259 (1997); *see AT&T Communications of Ill., Inc.*, 349 F.3d at 410 (nearly identical anti-preemption clause "precludes a reading that ousts the state legislature by implication."). In short, NYSRA's bid to wipe out New York's calorie labeling rule must sink or swim on the basis of the language of NLEA's express preemption provisions.[11]

[11] Even if Congress had not so clearly foreclosed implied preemption under the NLEA, NYSRA's argument—that New York's rule "interferes with the flexibility chosen by the FDA to encourage restaurants to provide nutrient information" (Br. at 16)—would fail on its own terms because "the FDA does not have regulatory authority to require nutrition information in restaurants" in the first place. *Keystone Report* at 74; *see FDA Calories Count Report* at V.B. Because "the FDA has no statutory authority under the NLEA to mandate nutritional disclosure by the fast food industry," "its reluctance may be explained simply by its lack of authority." Michael A. McCann, *Economic Efficiency and Consumer Choice Theory in Nutritional Labeling*, 2004 Wis. L. Rev. 1161, 1191 n.164 (2004).

"There is no federal pre-emption *in vacuo*." *Puerto Rico Dep't of Consumer Affairs*, 485 U.S. 495, 503 (1988); *see Pelman*, 237 F. Supp. 2d at 525-26 (rejecting McDonald's argument that Congress's decision not to impose mandatory nutrition labeling requirements on restaurants preempts state law nutrition labeling requirements for restaurants); *see also Sprietsma v. Mercury Marine*, 537 U.S. 51, 65 (2002) (holding that it is "quite wrong" to view the Coast Guard's decision not to require propeller guards on motor boats as the "functional equivalent" of a prohibition against state regulation of the subject matter; the decision was "fully consistent with an intent to preserve state regulatory authority"); *Freightliner Corp. v. Myrick*, 514 U.S. 280, 289 (1995) (where agency had no standard either requiring or prohibiting anti-lock brakes, state claim regarding anti-lock brakes was not preempted). Thus, that FDA has not required nutrition labeling by restaurants in no way precludes cities and states from doing so.

V. THE RESTAURANT ASSOCIATION'S FIRST AMENDMENT THEORY STANDS THE COMMERCIAL SPEECH DOCTRINE ON ITS HEAD.

To explain why the Restaurant Association's First Amendment theory fares no better than its preemption arguments, it would be difficult for us to improve upon Judge Walker's opinion in *National Electrical Manufacturers Association v. Sorrell*, 272 F.3d 104, 113-16 (2d Cir. 2001); *see also* Br. of *Amicus* Rudd Center. Instead, we pause only to note the breathtaking implications of the Association's position. In *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976), the first case to establish First Amendment protection for commercial speech, *amicus* Public Citizen represented the plaintiff consumer council, whose members wanted information about drugs so they could make informed decisions in the marketplace. The doctrine that has developed since then has consistently observed a "constitutional presumption favoring disclosure over concealment," *Ibanez v. Fla. Dep't. of Bus. and Prof'l Reg.*, 512 U.S. 136, 145 (1994), because "disclosure furthers, rather than hinders" First Amendment values: "Protection of the robust and free flow of accurate information is the principal First Amendment justification for protecting commercial speech." *Sorrell*, 272 F.3d at 114. It is for this reason that commercial disclosure requirements—including requirements justified by promotion of the public health—are assessed under the reasonable-relationship test of *Zauderer* rather than the intermediate-scrutiny standard of *Central Hudson*. *Id.* at 115 (citing *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985); *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557 (1980)); *cf. Rubin v. Coors Brewing Co.*, 514 U.S. 476, 484 (1995) (citing federal nutrition labeling requirements as evidence of a trend "favor[ing] greater disclosure of information, rather than less"). As the Second Circuit recognized in *Sorrell*, subjecting purely factual commercial disclosure requirements to heightened scrutiny would upend these settled principles and distort the commercial speech doctrine into a *barrier* to the free flow of information that may be critical to promoting public health. *Id.*

NYSRA's position, in fact, is even more radical than the position rejected in *Sorrell*, because it asks the Court to apply not just intermediate scrutiny, but *strict scrutiny*, on the theory that the New York rule constitutes "compelled speech" under *United States v. United Foods, Inc.,* 533 U.S. 405 (2001). To appreciate just how much NYSRA's position would disrupt settled law, it is worth considering how it would change the outcome not only in *Sorrell*, but in other cases that have adopted *Sorrell*'s approach in the face of compelled-speech challenges to various disclosure and posting laws. *See Envt'l Defense Center v. E.P.A.,* 344 F.3d 832, 848-851 (9th Cir. 2003) (upholding requirement that storm-sewer providers distribute information concerning the environmental hazards of stormwater discharges and steps the public can take to reduce pollutants in stormwater runoff); *UAW-Labor Employment & Training Corp. v. Chao*, 325 F.3d 360, 365 (D.C. Cir. 2003) (upholding requirement that federal contractors post notices at all of their facilities informing employees of rights under federal labor law that protect employees from being forced to join a union or to pay mandatory dues for costs unrelated to representational activities); *United States v. Wenger*, 292 F. Supp. 2d 1296, 1303-04 (D. Utah 2003) (upholding federal securities disclosure requirements). As these cases recognize, "the First Amendment's guarantee of freedom from 'compelled speech' is not absolute. Particularly in the commercial arena, the Constitution permits the State to require speakers to express certain messages without their consent, the most prominent examples being warning and nutritional information labels." *Entertainment Software Ass'n v. Blagovech*, 469 F.3d 641, 651 (7th Cir. 2006) (distinguishing between "opinion-based" compelled speech and "purely factual disclosures," such as "whether a particular chemical is within any given product"); *BellSouth Adver. & Pub. Corp. v. Tenn.*, 79 S.W.3d 506 (Tenn. 2002), *cert denied*, 537 U.S. 1189 (2003) (*Zauderer*, not *United Foods*, supplies the proper standard in cases involving factual commercial disclosure requirements); *see also Johanns v. Livestock Marketing Ass'n*, 544 U.S. 550, 557 (2005) (explaining that the Court has recognized only two kinds of compelled-speech cases: "true com-

pelled-speech cases," in which an individual must personally express an opinion with which he disagrees, and "compelled-subsidy cases," like *United Foods*.). Under NYSRA's expansive theory of compelled speech, however, countless federal, state and local laws on a wide range of subjects—from tobacco, pesticides, and pollutants, to hand-washing by restaurant employees—would be exposed to "searching scrutiny by unelected courts." *Sorrell*, 272 F.3d at 116. As Judge Walker noted in *Sorrell*, the mandatory nutrition labeling provisions of the NLEA would be among those laws. *Id.* (citing 21 U.S.C. 343(q)). "Such a result is neither wise nor constitutionally required." *Id.*

CONCLUSION

For the foregoing reasons, the Court should reject the New York State Restaurant Association's request to invalidate New York City Health Code Regulation 81.50.

Respectfully submitted,

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July 16, 2007

APPENDIX LISTING *AMICI CURIAE*

This brief is submitted on behalf of the following *amici*:

U.S. Representative Henry Waxman was the chief sponsor of the Nutrition Labeling and Education Act (NLEA) in the U.S. House of Representatives and has long been a leader in Congress on nutrition and food policy issues. He has represented California's 30th District since 1974 and is currently the Chairman of the House Committee on Oversight and Government Reform, which has oversight authority over all federal agencies, including the U.S. Food and Drug Administration.

David A. Kessler, M.D., was appointed Commissioner of the U.S. Food and Drug Administration by President George H.W. Bush in 1990. He was sworn in as Commissioner on the same day that President Bush signed the NLEA into law, was reappointed by President Clinton, and served through 1997, when he became Dean of the Yale School of Medicine. Dr. Kessler is currently Dean and Vice Chancellor for Medical Affairs at the University of California, San Francisco. Prior to his tenure at FDA, Dr. Kessler, who is also a lawyer, was a lecturer in food and drug law at Columbia Law School.

Public Citizen is a non-profit consumer advocacy organization with a longstanding interest in fighting exaggerated claims of federal preemption of state health and safety regulation and defending consumers' rights to know information that affects their health. Public Citizen's lawyers have represented parties and *amici* in the most significant federal preemption cases, *see e.g.*, *Riegel v. Medtronic*, -- S.Ct. --, *cert. granted*, June 25, 2007; *Bates v. Dow Agrosciences*, 544 U.S. 431, 449 (2005); *Medtronic v. Lohr*, 518 U.S. 470 (1996), and have also argued several seminal cases involving the commercial speech doctrine, *see e.g.*, *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748 (1976); *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985); *Edenfield v. Fane*, 507 U.S. 761 (1993).

Center for Science in the Public Interest (CSPI) is a national, non-profit advocacy organization for nutrition and health, food safety, and sound science. CSPI's advocacy was instrumental in getting Congress to consider nutrition labeling legislation in 1989 and in securing passage of the NLEA in 1990, and CSPI has tirelessly advocated for effective FDA enforcement of the NLEA in the seventeen years since its enactment. In addition, CSPI led the advocacy efforts on behalf of New York City's restaurant calorie labeling rule last year, and is working with other cities and states across the nation on similar measures.

The **American Medical Association**, an Illinois non-profit corporation, is the largest professional association of physicians and medical students in the United States. The AMA was founded in 1847 to promote the science and art of medicine and the betterment of public health, and these still remain its core purposes. Its members practice in every state, including New York, and in every specialty. In June 2007, the AMA, concerned by the alarming incidence of obesity and of obesity-related medical conditions, specifically resolved that calorie

content, in addition to other nutrition information, be displayed on menus and menu boards in fast-food and other chain restaurants.[12]

The **American College of Preventive Medicine**, established in 1954, is the national professional society for physicians committed to disease prevention and health promotion. To address the lack of nutrition labeling and the rising obesity rates in adults and children, ACPM introduced the menu-labeling resolution that was passed by the AMA's House of Delegates last month.

The **American Diabetes Association** is a nationwide non-profit organization founded in 1940 to advance the interests of the now nearly 21 million Americans with diabetes. ADA's mission is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. It is the nation's leading voluntary health organization supporting diabetes research, information and advocacy. ADA believes that providing calorie information available through postings on menu boards is a critical step in helping people get the information they need to understand how foods they eat impact their weight and overall nutrition goals.

The **American Public Health Association** is the oldest, largest and most diverse organization of public health professionals in the world and has been working to improve public health since 1872. The Association aims to protect all Americans and their communities from preventable, serious health threats. APHA believes that requiring nutrition labeling at fast-food and other chain restaurants is particularly important given how many of our calories are consumed at restaurants, the large portion sizes and high calorie contents often served at restaurants, and the lack of nutrition information at restaurants.

California Center for Public Health Advocacy is a non-profit organization established in 1999 by California's two public health associations to raise awareness about critical public health issues and is currently the lead supporter of a bill before the California State Legislature to require nutrition labeling on menus and menu boards in chain restaurants.

The Medical Society of the State of New York, an organization of approximately 30,000 licensed physicians, medical residents, and medical students in New York State, is committed to representing the medical profession as a whole and advocating on its behalf concerning health-related rights, responsibilities, and issues.

Trust for America's Health is a non-profit, non-partisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority.

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[12] The AMA and Medical Society of the State of New York join this brief both in their own persons and as representatives of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center was formed in 1995 as a coalition of the AMA and private, voluntary, nonprofit state medical societies to represent the views of organized medicine in the courts.

George L. Blackburn, M.D., Ph.D., holds the S. Daniel Abraham Chair in Nutrition Medicine at Harvard Medical School, where his research focuses on obesity and clinical nutrition. He is also the Chief of the Nutrition Laboratory and Director of the Center for the Study of Nutrition Medicine at the Beth Israel Deaconess Medical Center, Boston.

Richard J. Deckelbaum, M.D., is the Robert R. Williams Professor of Nutrition, Chairman of the Institute of Human Nutrition, and Professor of Pediatrics and Epidemiology at Columbia University's Mailman School of Public Health and College of Physicians and Surgeons, where his research focuses on translating basic nutritional questions into lipid and cellular biology.

Penny M. Kris-Etherton, Ph.D., is Distinguished Professor of Nutrition at Pennsylvania State University, where her research focuses on effects of diet on metabolism and platelet function.

Francine R. Kaufman, M.D., is Director of the Comprehensive Childhood Diabetes Center at Children's Hospital Los Angeles and Professor of Pediatrics at the University of Southern California School of Medicine. She is an expert on childhood diabetes-obesity epidemic and the author of *Diabesity* (2005).

Alice H. Lichtenstein, D.Sc., is the Stanley N. Gershoff Professor of Nutrition Science and Policy and Professor of Public Health and Family Medicine at Tufts University, as well as Senior Scientist and Director of the Cardiovascular Nutrition Laboratory at the Jean Mayer USDA Human Nutrition Research Center on Aging. Her research examines the effect of diet on disease risk factors.

Marion Nestle, Ph.D., M.P.H., is the Paulette Goddard Professor of Nutrition, Food Studies, and Public Health at New York University, where her research focuses on the role of food marketing as a determinant of dietary choice. Her books include *Food Politics: How the Food Industry Influences Nutrition and Health* (2002, revised 2007); and *What to Eat* (2006).

Barry M. Popkin, Ph.D., is the Carla Steel Chamblee Distinguished Professor of Global Nutrition at the University of North Carolina, Chapel Hill, where he directs the Interdisciplinary Center for Obesity and the Division of Nutrition Epidemiology and studies dynamic changes in diet, physical activity, and body composition, with a focus on rapid changes in obesity.

Walter Willett, M.D., M.P.H., Dr.P.H., is the Fredrick John Stare Professor of Epidemiology and Nutrition at the Harvard School of Public Health, Professor of Medicine at Harvard Medical School, and the author of *Eat, Drink, and Be Healthy: The Harvard Medical School Guide to Healthy Eating.* He is also one of the principal investigators on the Nurses Health Study, one of the largest, long-term studies to look at the effect of diet on health.

APPENDIX OF STATUTORY AND REGULATORY PROVISIONS

24 RCNY Health Code Reg. § 81.50. Calorie labeling.

(a) Scope and applicability. This section shall apply to menu items that are served in portions the size and content of which are standardized and for which calorie content information is made publicly available on or after March 1, 2007, by or on behalf of the food service establishment serving the items.

(b) Calorie information for menu items. Food service establishments shall post on menu boards and menus the calorie content values (in kcal) that have been made publicly available as specified in subdivision (a) for each menu item next to the listing of each menu item. Posted calorie content shall be calculated in accordance with 21 CFR § 101.9(c)(1)(i) or its successor regulation. Subject to prior approval by the Department, food service establishments may use alternative means for making calorie information available to patrons, provided such information is made available at the point of purchase and is at least as prominent as required in paragraph (1) below.

(1) Menu boards and menus. The term "calories" or "cal" shall appear as a heading above a column listing the calorie content value of each menu item, or adjacent to the calorie content value for each menu item, in the same or larger typeface as the calorie content values for individual menu items.

(A) Menu boards. On menu boards, calorie content values shall be posted in a size and typeface at least as large as the name of the menu item or price, whichever is larger.

(B) Menus. On printed menus, calorie content values shall be legible and shall be printed in a size and typeface at least as large as the name or price of the menu item.

(2) Range of calorie content values for different flavors and varieties. For menu items that come in different flavors and varieties but that are listed as a single menu item, including, but not limited to, beverages, ice cream, pizza or doughnuts, the range of calorie content values showing the minimum to maximum numbers of calories for all flavors or varieties of that item shall be listed on menu boards and menus for each size offered for sale.

(c) Effective date. This section shall take effect on July 1, 2007.

21 U.S.C. § 343. Misbranded food.

A food shall be deemed to be misbranded--

21 U.S.C. § 343(q). Nutrition information

(1) Except as provided in subparagraphs (3), (4), and (5), if it is a food intended for human consumption and is offered for sale, unless its label or labeling bears nutrition information that provides--

* * *

(C) the total number of calories--
(i) derived from any source, and
(ii) derived from the total fat,
in each serving size or other unit of measure of the food,

* * *

(5)(A) Subparagraphs (1), (2), (3), and (4) shall not apply to food—
(i) which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments[.]

21 U.S.C. § 343(r). Nutrition levels and health-related claims

(1) Except as provided in clauses (A) through (C) of subparagraph (5), if it is a food intended for human consumption which is offered for sale and for which a claim is made in the label or labeling of the food which expressly or by implication--

(A) characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food unless the claim is made in accordance with subparagraph (2), or

(B) characterizes the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food to a disease or a health-related condition unless the claim is made in accordance with subparagraph (3) or (5)(D).

A statement of the type required by paragraph (q) of this section that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph and a claim subject to clause (A) is not subject to clause (B).

(2)(A) Except as provided in subparagraphs (4)(A)(ii) and (4)(A)(iii) and clauses (A) through (C) of subparagraph (5), a claim described in subparagraph (1)(A)--

(i) may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary[.]

21 U.S.C. §§ 343-1. National uniform nutrition labeling

(a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—

* * *

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title, except a requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 343(q)(5)(A) of this title, or

(5) any requirement respecting any claim of the type described in section 343(r)(1) of this title, made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title.

21 U.S.C. § 343-1, note

The Nutrition Labeling and Education Act of 1990 shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A [21 U.S.C. 343-1(a)] of the Federal Food, Drug, and Cosmetic Act.

21 C.F.R. 101.10. Nutrition labeling of restaurant foods.

Nutrition labeling in accordance with § 101.9 shall be provided upon request for any restaurant food or meal for which a nutrient content claim (as defined in § 101.13 or in subpart D of this part) or a health claim (as defined in § 101.14 and permitted by a regulation in subpart E of this part) is made, except that information on the nutrient amounts that are the basis for the claim (e.g., "low fat, this meal provides less than 10 grams of fat") may serve as the functional equivalent of complete nutrition information as described in § 101.9. Nutrient levels may be determined by nutrient data bases, cookbooks, or analyses or by other reasonable bases that provide assurance that the food or meal meets the nutrient requirements for the claim. Presentation of nutrition labeling may be in various forms, including those provided in § 101.45 and other reasonable means.

21 C.F.R. 101.13. Nutrition content claims—General principles

(a) This section and the regulations in subpart D of this part apply to foods that are intended for human consumption and that are offered for sale, including conventional foods and dietary supplements.

(b) A claim that expressly or implicitly characterizes the level of a nutrient of the type required to be in nutrition labeling under § 101.9 or under § 101.36 (that is, a nutrient content claim) may not be made on the label or in labeling of foods unless the claim is made in accordance with this regulation and with the applicable regulations in subpart D of this part or in part 105 or part 107 of this chapter.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., "low sodium" or "contains 100 calories."

(2) An implied nutrient content claim is any claim that:

(i) Describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"); or

(ii) Suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams (g) of fat").

* * *

(i) Except as provided in § 101.9 or § 101.36, as applicable, or in paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

* * *

(3) The statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect (e.g., "100 calories" or "5 grams of fat"), in which case no disclaimer is required.

21 C.F.R. 101.60. Nutrient content claims for the calorie content of foods.

(a) *General requirements.* A claim about the calorie or sugar content of a food may only be made on the label or in the labeling of a food if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13;

(3) The food for which the claim is made is labeled in accordance with § 101.9, § 101.10, or § 101.36, as applicable; and

(4) For dietary supplements, claims regarding calories may not be made on products that meet the criteria in § 101.60(b)(1) or (b)(2) for "calorie free" or "low calorie" claims except when an equivalent amount of a similar dietary supplement (e.g., another protein supplement) that the labeled food resembles and for which it substitutes, normally exceeds the definition for "low calorie" in § 101.60(b)(2).

(b) *Calorie content claims.* (1) The terms "calorie free," "free of calories," "no calories," "zero calories," "without calories," "trivial source of calories," "negligible source of calories," or "dietarily insignificant source of calories" may be used on the label or in the labeling of foods, provided that:

(i) The food contains less than 5 calories per reference amount customarily consumed and per labeled serving.

(ii) As required in § 101.13(e)(2), if the food meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to disclose that calories are not usually present in the food (e.g., "cider vinegar, a calorie free food").

(2) The terms "low calorie," "few calories," "contains a small amount of calories," "low source of calories," or "low in calories" may be used on the label or in labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i)(A) The food has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons and does not provide more than 40 calories per reference amount customarily consumed; or

(B) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and does not provide more than 40 calories per reference amount customarily consumed and, except for sugar substitutes, per 50 g (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50 g criterion refers to the "as prepared" form).

(ii) If a food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the caloric content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "celery, a low calorie food").

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of meal products as defined in § 101.13(l) or main dish products as defined in § 101.13(m), provided that:

(i) The product contains 120 calories or less per 100 g; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the calorie content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which it attaches.

(4) The terms "reduced calorie," "reduced in calories," "calorie reduced," "fewer calories," "lower calorie," or "lower in calories" may be used on the label or in the labeling of foods, except as limited by § 101.13(j)(1)(i) and except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent fewer calories per reference amount customarily consumed than an appropriate reference food as described in § 101.13(j)(1); and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the calories differ between the two foods are declared in immediate proximity to the most prominent such claim (e.g., reduced calorie cupcakes "33 1/3 percent fewer calories than regular cupcakes"); and

(B) Quantitative information comparing the level of the nutrient per labeled serving size with that of the reference food that it replaces (e.g., "Calorie content has been reduced from 150 to 100 calories per serving.") is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or labeling of foods if the reference food meets the definition for "low calorie."

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent fewer calories per 100 g of food than an appropriate reference food as described in § 101.13(j)(1); and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the calories differ between the two foods are declared in immediate proximity to the most prominent such claim (e.g., Larry's Reduced Calorie Lasagna, "25 percent fewer calories per oz (or 3 oz) than our regular Lasagna"); and

(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference food that it replaces (e.g., "Calorie content has been reduced from 108 calories per 3 oz to 83 calories per 3 oz.") is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or labeling of food if the reference food meets the definition for "low calorie."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Food and Drug Administration
College Park, MD 20740

APR 14 2006

Michael E. Jacobson, Ph.D.
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Dear Dr. Jacobson:

This is in response to your letter dated March 14, 2006 to the Food and Drug Administration (FDA). In this letter, you urge the FDA to take prompt action to halt misleading *trans* fat claims on foods that contain significant levels of saturated fat. You state these claims are misleading under section 403(a) and 201(n) of the Federal Food, Drug and Cosmetic Act (the Act). You state that FDA withdrew definitions for nutrient content claims for *trans* fat (68 FR 41434) and simultaneously issued an Advanced Notice of Proposed Rulemaking (ANPRM) to solicit information and data that could be used to establish new nutrient content claims about *trans* fat.

As examples, you list food products that state "0g *trans* fat" (or similar statements) on the principal display panel while the Nutrition Facts panel declares an appreciable amount of saturated fat (i.e., 7g, 11g, 4g, 5g, 6g). You refer to these statements (i.e., "0g *trans* fat") as claims. You further state that consumers expect that a product labeled with these statements to be free of saturated fat.

You are correct that there are no approved nutrient content claims for *trans* fat. As explained in the ANPRM that issued July 11, 2003 (68 FR 41507), the level of scientific evidence does not currently support the establishment of an appropriate reference value for daily consumption of *trans* fat; therefore, FDA withdrew the proposed definitions for *trans* fat free, reduced *trans* fat, and limits on the amount of *trans* fat wherever saturated fat limits are placed on nutrient content claims. The ANPRM, in part, solicited information and data that potentially could be used to establish new nutrient content claims for *trans* fat. FDA supports consumer testing to ensure that any claims about *trans* fat, alone or in combination with other nutrients, such as saturated fat and cholesterol, provides meaningful guidance to consumers and drives the market in a nutritionally beneficial direction. Thus, FDA plans to conduct consumer research in the future to evaluate consumer understanding of "*trans* fat free" and "reduced *trans* fat"

nutrient content claims on product with varying nutritional characteristics (i.e., saturated fat, cholesterol). However, as noted in the ANPRM (at page 41509), if a company wants to make a statement about the fat content of a product that is demonstrably true, balanced, adequately substantiated, and not misleading, FDA would consider the exercise of its enforcement discretion. The FDA has not received any such request or information.

While nutrient content claims for *trans* fat are being considered, the label or labeling may contain a factual statement about the amount or percentage of a nutrient in accordance with 21 CFR 101.13(i)(3). The use of this kind of factual statement should not in any way imply that there is a little or a lot of the nutrient in the food and is not false or misleading under section 403(a) of the Act. For example, "0g *trans* fat" and "2g *trans* fat" are appropriate when, in fact, the Nutrition Facts panel represents the same amount. The use of a percentage is moot since there is no percent Daily Value (%DV) for *trans* fat. The use of descriptive words, such as "only" or "contains," would implicitly characterize the level of the nutrient for which there is no definition. A claim that expressly or implicitly characterizes the level of a nutrient may not be made on the label or in labeling of foods unless the claim is made in accordance with the regulations (21 CFR 101.13(b)). As mentioned above, there are no approved claims for *trans* fat that characterize the level.

The "0g *trans* fat" statements presented in your letter are considered factual statements, rather than nutrient content claims, in accordance with § 101.13(i)(3) and the products are not considered misbranded under the Act. In the future, FDA hopes to develop *trans* fat nutrient content claims based on evolving science and the results of consumer research to provide meaningful guidance to consumers for choosing healthy foods.

Sincerely,

Barbara Schneeman

Barbara O. Schneeman, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

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JUN - 4 2001

WARNING LETTER
ONPLDS 11-01

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Doug Levin
CEO
Fresh Samantha® Inc.
84 Industrial Park Road
Saco, Maine 04072

Dear Mr. Levin:

The Food and Drug Administration (FDA) has reviewed the label of your "Fresh Samantha® Super Juice with Echinacea." We have concluded that this product is in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR), Part 101-Food Labeling.

The product is misbranded under section 403(r)(1)(A) of the Act (21 U.S.C. 343(r)(1)(A)) because the label bears the unauthorized nutrient content claims "with Echinacea" and "... contains Echinacea..." "Contains" is a nutrient content claim defined in 21 CFR 101.54(c). FDA considers "with" to be a synonym for "contains" in the context used on this label. The claim "contains" is authorized for nutrients that have a Reference Daily Intake (RDI) (see 21 CFR 101.9(c)(8)(iv) or Daily Reference Value (DRV) (see 21 CFR 101.9(c)(9)), provided that the food that bears the claim contains 10-19 percent of the RDI or DRV per reference amount customarily consumed (see 21 CFR 101.54(c)). This claim is not authorized for substances without an RDI or DRV. Since there is no RDI or DRV for Echinacea, the claims "with Echinacea" and "...contains Echinacea" are not authorized and thus, misbrand your product.

The product is also misbranded under section 403(a)(1) of the Act (21 U.S.C. 343(a)(1)) because the product name "Fresh Samantha®" falsely implies that the finished product is "fresh" when in fact it has been thermally processed (pasteurized). Products that have been thermally processed do not meet the definition for "fresh" (*see* 21 CFR 101.95).

Under the Act, any substance intentionally added to a conventional food, such as juice products like Fresh Samantha® Super Juice, must be used in accordance with a food additive regulation unless the substance is the subject of a prior sanction, or is generally recognized as safe (GRAS) among qualified experts for its intended use in foods. A substance added to food that is not the subject of a prior sanction, is not GRAS for its intended use, and is not

used in accordance with a food additive regulation causes the food containing the substance to be adulterated under section 402(a)(2)(C) of the Act (21 U.S.C. 342(a)(2)(C)). Such a food cannot be legally marketed in the United States. We are not aware of a basis for concluding that Echinacea is prior sanctioned or is GRAS for use in juice products.

The above violations are not meant to be an all-inclusive list of deficiencies in your product and its labeling. It is your responsibility to ensure that all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Your letter should also include your basis for concluding that Echinacea is the subject of a prior sanction or is GRAS for use in conventional foods. Copies of revised labels for the products should also be submitted. If corrective actions cannot be completed within 15 working days, state the reasons for delay and the time within which corrections will be completed.

You should direct your written reply to me at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810), 200 C Street S.W., Washington, D.C. 20204.

Sincerely yours,

/s/

John B. Foret
Director
Division of Compliance
and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

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MAY 15 2000

WARNING LETTER
ONPLDS 02-00

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John Ferolito
President
Ferolito, Vultaggio & Sons, Inc.
5 Dakota Drive
Suite 205
Lake Success, New York 11042

Dear Mr. Ferolito:

The Food and Drug Administration (FDA) has reviewed the label for your "Arizona Rx Stress Relief Elixir." Our review reveals that this label causes the product to be in violation of section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

This product is misbranded within the meaning of section 403(r)(1)(A) of the Act in that the label bears nutrient content claims that are not authorized by regulation or the Act or are not consistent with an authorizing regulation. The claims include "...ENHANCED WITH PANAX GINSENG•KAVA-KAVA•CHAMOMILE•VALERIAN ..." and "...FORTIFIED WITH ...MINERALS." In the context used on this label the term "enhanced" is considered to be an unauthorized synonym for "added."

FDA has defined the nutrient content claim "added" in 21 CFR 101.54(e). "Added" can be used to describe the level of protein, vitamins, minerals, dietary fiber, or potassium, nutrients for which there are established reference values. There are no established reference values for Panax Ginseng, Kava-Kava, Chamomile or Valerian. Since Panax Ginseng, Kava-Kava, Chamomile and Valerian are not one of the substances included in 21 CFR 101.54(e), the claim "ENHANCED WITH PANAX GINSENG•KAVA-KAVA•CHAMOMILE•VALERIAN" is not authorized. Because the claim is not authorized as a nutrient content claim by regulation or by the Act, the claim misbrands the product.

The claim "fortified with ... minerals" is not consistent with the regulation governing use of the claim "fortified." "Fortified" may be used on the label of foods, in part, to describe the level of specific minerals provided that the food contains at least 10 percent more of the RDI for each mineral per reference amount customarily consumed than an appropriate

reference food (21 CFR 101.54(e)). The reference amount customarily consumed for a beverage is 240 ml. The only mineral declared on the product label is calcium and the nutrition information states that calcium is present at a level of only 1% of the RDI per 8 fluid ounces. Because the use of the claim is not consistent with the regulation governing the term "fortified," the claim misbrands the product.

The product is further misbranded within the meaning of section 403(a)(1) of the Act. The label bears the "Rx" symbol in several locations and also bears statements, such as, "RX STRESS," "RELIEF ELIXIR," "A SAFE AND CERTAIN REMEDY" and "Rx STRESS REMEDY" that in the context of the labeling as a whole suggest that this is a prescription product. If your intention is to market this product as a food, the label must be revised so that the prescription symbols and the other phrases and terms that suggest this product is a Rx drug are removed from this label. In addition, the statement of identity must appear as one of the principal features on the principal display panel in accordance with the requirements in 21 CFR 101.3.

The above violations are not meant to be an all inclusive list of deficiencies on your product labels. It is your responsibility to assure that all of your products are labeled in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

We also point out that any ingredient intentionally added to a conventional food such as this beverage or any of your other products must be used in accordance with a food additive regulation, unless it is generally recognized as safe (GRAS) among qualified experts for its intended use. The use of a food ingredient that is neither GRAS nor an approved food additive causes a food to be adulterated under section 402(a)(2)(C) of the Act. You must assure that the ingredients used in your products are either GRAS for their intended use or used in accordance with a food additive regulation.

Please notify this office within 15 working days of receipt of this letter, of the specific steps you have taken or plan to take to correct the noted violations. Copies of revised labels for the products should also be submitted. If corrective actions cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

You should direct your written reply to me at the Food and Drug Administration, Office of Nutritional Products, Labeling, and Dietary Supplements, 200 C Street, S.W., Washington, D.C. 20204.

Sincerely yours,

/S/

John B. Foret
Director
Division of Compliance
and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M3388n

Food and Drug Administration
Washington DC 20204

WARNING LETTER
OFL-01-00

JAN 27 2000

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert Ehrlich
President
Robert's American Gourmet
20 Lumber Rd
Roslyn Heights, New York 11577

Dear Mr. Ehrlich:

The Food and Drug Administration (FDA) has reviewed labels for some of your products including the labels for Spirulina Spirals A Vegetarian Snack and Low Fat Fruity Booty A Whole Food Supplement. Our review reveals that these labels cause the above products to be in violation of section 403 of the Federal Food, Drug, and Cosmetic Act (the act), and Title 21, Code of Federal Regulations (21 CFR), Part 101 – Food Labeling, as follows:

Spirulina Spirals A Vegetarian Snack

The product is misbranded within the meaning of section 403(q) of the act in that it bears the nutrient content claim "Spriulina provides Vitamin B12" but fails to declare the level of vitamin B12 expressed as a percentage of the Reference Daily Intake (RDI) in the nutrition information in accordance with the requirements of 21 CFR 101.9(c)(8)(ii). In addition, the claim "Spirulina provides Vitamin B12" implies that this snack product is a good source of Vitamin B12. "Good source" as defined in 21 CFR 101.54(c) requires, in part, that the product contains 10-19% of the RDI of Vitamin B12 per reference amount customarily consumed. The reference amount customarily consumed for snack foods is 30 grams. Unless the Spirulina Spirals contain at least 10% of the RDI of vitamin B12 per 30 grams of product, the statement "Spriulina provides Vitamin B12" would serve to misbrand the product under Section 403(r)(1)(A) of the Act.

Low Fat Fruity Booty A Whole Food Supplement

The product is misbranded within the meaning of section 403(a) of the act in that it bears the statement "Everyone should eat more fruits and Fruity Booty is a great way to start," which falsely suggests that this product is mostly fruit. The product is a rice and corn snack food that claims to contain approximately 200 mg of "fruit" ingredient per serving.

In addition, we reviewed the label for Echinacea Shells A Vegetarian Snack. The label for this food bears the claim "Echinacea facilitates the healing process and is used as a "blood purifier" and can be an effective antibiotic" that suggests this product is intended to treat, cure, mitigate, or prevent disease. This claim suggests that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act and thus would be subject to regulation under the drug provisions of the act.

The above violations are not meant to be an all inclusive list of deficiencies on your labels. It is your responsibility to assure that all of your products are labeled in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

We also note that under the act, any ingredient intentionally added to a conventional food like these snacks must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. A food ingredient that is not GRAS or approved as a food additive causes a food to be adulterated under section 402(a)(2)(C) of the act and cannot be legally marketed in the U.S. We note that ingredients such as Ehinacea, *Ginkgo Biloba*, St. John's Wort, cats claw, kava kava, and Spirulina are listed on the labels of several of your products. FDA has not issued a food additive regulation authorizing the use of these ingredients in food. Additionally, we are not aware of a basis for concluding that these ingredients are GRAS for use in conventional food.

In addition to the items identified above, we are also concerned about other statements on the labels of your products that describe the effects of certain substances on the structure or function of the body. These include "Spirulina provides ...oxygen for the blood...," "Spirulina... is actually an appetite suppressant," "Ginkgo Biloba has shown to Increase Blood Flow to the Brain which can Increase MEMORY AND ALERTNESS, PROMOTES RELAXATION," and "A Memory Snack." A food label or labeling may bear statements about a substance's effect on the structure or function of the body, however, such effects on the structure or function of the body must be achieved through nutritive value and a statement about the effects may not claim to diagnose, mitigate, treat, cure, or prevent disease. The above claims may not appear on these food labels unless they are truthful and not misleading and the claimed effect is achieved through nutritive value. A structure-function claim on a food that is not achieved through nutritive value renders the product a drug under section 201(g)(1)(C) of the act.

We have the following additional labeling comments:

> Since the product Fruity Booty is a snack food, the phrase "A Whole Food Supplement" is inappropriate as part of the statement of identity. In addition, the term "Whole Food Concentrates" is not the common or usual name for an ingredient and the phrase "...whole food snack..." has no meaning and may be confusing. We also question the use

of the phrase "& Citrus Blends" on this label since the ingredient statement only lists one citrus ingredient.

The ingredient and manufacture's statements on the Echinacea Shells and the Spirulina Spirals labels are not prominent or conspicuous because they lack sufficient background contrast (See 21 CFR 101.15).

The net weight statements on several of your labels, including the Grateful Puffs, Echinacea Shells, and Spirulina Spirals are not located in the bottom 30% of the area of the label panel. (See 21 CFR 101.105(f)).

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken or plan to take to correct the noted violations. Your letter should also include your basis for concluding that the structure and function claims on your products and the ingredients you use meet the requirements as outlined above. Copies of revised labels for the products should also be submitted. If corrective actions cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

You should direct your written reply to me at: the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Food Labeling (HFS-150), 200 C Street, S.W., Washington, D.C. 20204.

Sincerely yours,

/S/

John B. Foret
Director
Division of Programs
and Enforcement Policy
Office of Food Labeling
Center for Food Safety
and Applied Nutrition

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

WARNING LETTER
OFL 01-99

CORRECTION
VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 28, 1999

Mr. David Langer
Vice President
Langers Juice Co.
16195 Stephens Street
City of Industry, California 91745

Dear Mr. Langer:

FDA has reviewed labels for several of your juice products and find that these products bear claims that misbrand the products under section 403 of the Federal Food, Drug, and Cosmetic Act (the act) and that may render the products drugs under section 201(g) of the act.

Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease are drugs under section 201(g)(1)(B) of the act. Accordingly, a statement on a food label or in its labeling that claims the food is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease makes the product bearing the statement a drug under section 201(g)(1)(B) of the act. Under section 403(r) of the act, however, food labels and labeling may bear authorized health claims. A health claim is a claim characterizing the relationship between a substance and a disease. FDA authorizes health claims following the submission of a petition and promulgation of a regulation. In addition, the act authorizes health claims based on authoritative statements through a notification procedure set out in section 403(r)(3)(C) of the act. A food bearing a health claim that is not authorized by regulation or the act misbrands the product under section 403(r) of the act.

In addition, articles, other than a food, that are intended to affect the structure or function of the body of man are drugs under section 201(g)(1)(C) of the act. Accordingly, a food label or labeling may bear statements about a substance's effect on the structure or function of the body. Such effects on the structure or function of the body must be achieved through nutritive value and the statement about the effects may not claim to diagnose, mitigate, treat, cure, or prevent disease. A structure-function claim on a food that is not achieved through nutritive value renders the product a drug under section 201(g)(1)(C) of the act.

Food labels and labeling may also bear authorized nutrient content claims under section 403(r) of the act. A nutrient content claim is a claim characterizing the level of a nutrient in a food.

Like health claims, FDA authorizes nutrient content claims following the submission of a petition and promulgation of a regulation and the act authorizes nutrient content claims based on authoritative statements through a notification procedure set out in section 403(r)(2)(G) of the act. A food bearing a nutrient content claim that has not been authorized by regulation or the act misbrands the product under section 403(r) of the act.

1. White Grape [Juice from concentrate] with Essential Antioxidants Vitamin C & Grape Seed Extract

This product is misbranded within the meaning of section 403(r)(1)(B) of the act in that the label bears unauthorized health claims. The claims include "Protect your heart as you quench your thirst," "Flavonoids... inside grape skins and seeds... help lower bad cholesterol, keep arteries open and decrease cancer risk...," and a claim that compares the effect on the body of your product to "the heart-protecting strength in a glass of red wine." Because the claims on this product are not authorized as health claims by regulation or by the act, the claims misbrand the product.

hc

This product is also misbranded within the meaning of section 403(r)(1)(A) of the act in that the label bears unauthorized nutrient content claims. The claims include "just as many flavonoids as purple grape juice" and "two glasses equal the...strength in a glass of red wine." Such claims imply that both foods are good sources of flavonoids. Since there is no daily value established for flavonoids these claims can not be authorized. Because the claims on this product are not authorized as nutrient content claims by regulation or by the act, the claims misbrand the product.

This product is also misbranded within the meaning of section 403(a) of the act in that the label bears the claim "with Essential Antioxidants....GRAPE SEED EXTRACT...," which suggests that grape seed extract is an essential nutrient. Because grape seed extract is not an essential nutrient, the claim misbrands the juice.

2. Grape Juice with Essential Antioxidants Vitamin C & Grape Seed Extract

This product is misbranded within the meaning of section 403(r)(1)(B) of the act in that the label bears unauthorized health claims. The claims include "Protect your heart as you quench your thirst," "heart-healthy benefits of red wine," and "Flavonoids...inside grape skins and seeds...help lower bad cholesterol, keep arteries open and decrease the risk of cancer...." Because the claims on this product are not authorized as health claims by regulation or by the act, the claims misbrand the product.

This product is also misbranded within the meaning of section 403(r)(1)(A) of the act in that the label bears unauthorized nutrient content claims. The claims include the statement "...twice the flavonoids of regular purple grape juice" and "just as many as a glass of red wine." Such claims imply that both foods are good sources of flavonoids. Since there is no daily value established for flavonoids these claim can not be authorized. Because the claims on this product are not authorized as nutrient content claims by

regulation or by the act, the claims misbrand the product.

This product is also misbranded within the meaning of section 403(a) of the act in that the label bears the claim "with Essential Antioxidants...GRAPE SEED EXTRACT" which suggests that grape seed extract is an essential nutrient. Because grape seed extract is not an essential nutrient, the claim misbrands the juice.

3. Cranberry Grape 100 with Essential Antioxidants Vitamins A, C, & E, Grape Seed Extract and Co Enzyme Q10 and Magnesium

This product is misbranded within the meaning of section 403(r)(1)(B) of the act in that the label bears unauthorized health claims. The claims include "Antioxidants help protect your immune system from free radicals, unstable molecules that contribute to disease and aging," "The flavonoids in purple grapes...help lower bad cholesterol," "the heart-protecting power of a glass of red wine," and "We added...magnesium, which helps prevent certain cancers...." Because the claims on this product are not authorized as health claims by regulation or by the act, the claims misbrand the product.

hc

This product is also misbranded within the meaning of section 403(r)(1)(A) of the act in that the label bears unauthorized nutrient content claims. The claims include "Each glass...equals the...power of a glass of red wine" and "We added co enzyme Q-10...." Since there is no daily value established for flavonoids or co-enzyme Q-10 these claims can not be authorized. Because the claims are not authorized as nutrient content claims by regulation or by the act, the claims misbrand the product.

nut con

This product is also misbranded within the meaning of section 403(a) of the act in that the label bears the claim "It's the grape seed extract and other essential antioxidants" which suggests that grape seed extract is an essential nutrient. Because grape seed extract is not an essential nutrient, the claim misbrands the juice. In addition, the claim "NO...FLAVORS...ADDED" misbrands the product under section 403(a) of the act because the ingredient statement declares "natural flavors."

4. Raspberry Cranberry 100 with Essential Antioxidants Vitamins A, C, & E, Gingko Biloba, Ginseng, and Potassium

This product is misbranded within the meaning of section 403(r)(1)(B) of the act in that the label bears unauthorized health claims. The claims include "Antioxidants help protect your immune system from free radicals, highly unstable molecules that contribute to disease and aging" and "A diet rich in these vitamins has also been associated with decreased cancer risk." Because the claims on this product are not authorized as health claims by regulation or by the act, the claims misbrand the product.

This product is also misbranded within the meaning of section 403(r)(1)(A) of the act in that the label claims that the product contains "added gingko biloba" and "Plus, ginseng (American and Siberian)." Since there is no daily value established for ginko biloba and ginseng these claims can not be authorized. Because these statements are not authorized as nutrient content claims by regulation or by the act, the statements misbrand the product.

This product is also misbranded within the meaning of section 403(a) of the act in that the label bears the claim "NO...FLAVORS...ADDED" while the ingredient statement declares "Natural Flavors."

5. Cranberry 100 With Essential Antioxidants Vitamins A, C, & E and Calcium Added

This product is misbranded within the meaning of section 403(r)(1)(B) of the act in that it bears an unauthorized health claim. The claim is "Antioxidants help protect your immune system, and a diet rich in these vitamins is associated with decreased risks of several types of cancer." Because this claim is not authorized by regulation or by the act as a health claim, this claim misbrands the product.

6. Coldbuster 100 Essential antioxidants, Vitamins A and C, with Echinacea & Zinc

The product label bears statements that suggest that the product is intended to treat, prevent, cure, or mitigate disease, namely the common cold. These claims suggest that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act. In addition to the product's name, "Coldbuster," the claims suggesting that this product is intended for use as a drug include "ColdBuster 100 is just what the doctor ordered. At the first sign of a cold, pour yourself a glass of this delicious, immune-boosting juice. We've loaded it with nature's best cold fighters: echinacea, zinc and vitamins A & C. [E]chinacea is a plant known for its healing, anti-viral properties; zinc shortens the duration of a cold, and Vitamins A&C help you fight infections and strengthen your immune system. Together, they can deliver your cold a knockout punch...So when you feel the sniffles or a sore throat coming on,...Cold Buster 100 is the perfect prescription." Because these statements suggest that the product is intended to treat, cure, mitigate, or prevent the common cold, they suggest that this product is subject to regulation under the drug provisions of the act.

The above violations are not meant to be an all inclusive list of deficiencies on your labels. It is your responsibility to assure that all of your products are labeled in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

In addition to the claims identified above, we are also concerned about other statements on the labels of your products that describe the effects of certain substances on the body. For example, claims on your products include suggestions that certain ingredients provide "brain-boosting

power to enhance memory and circulation" and "increase energy and longevity." As discussed at the beginning of this letter, such claims must be in the form of an appropriate claim to affect the structure or function of the body and the claimed effect must be achieved through nutritive value.

Stm of law

We also note that under the act, any ingredient intentionally added to a conventional food like these juices must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. A food ingredient that is not GRAS or approved causes a food to be adulterated under section 402(a)(2)(C) of the act and cannot be legally marketed in the U.S. We note that ingredients such as echinacea, grape seed extract, and gingko biloba are listed on the labels of several of these juices. FDA has not issued a food additive regulation authorizing the use of these ingredients in food. Additionally, we are not aware of a basis for concluding that these ingredients are GRAS for use in conventional food.

Left out ginseng

Please notify the FDA Los Angeles District office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Your letter should also include your basis for concluding that the claims on your product and the ingredients you use meet the requirements as outlined above. Copies of revised labels for the products should also be submitted. If corrective actions cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

You should direct your written reply to the Food and Drug Administration, Los Angeles District, 19900 MacArthur Blvd, Suite 300, Irvine, CA 92612, attn: Mr. Thomas Sawyer.

Sincerely yours,

John B. Foret

John B. Foret
Director
Division of Programs
and Enforcement Policy
Office of Food Labeling
Center for Food Safety
and Applied Nutrition